K040409

FEB 27 2004

510(k) Summary for
Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System

1. SPONSOR

Larsen & Toubro Limited
Medical Equipment & Systems SBU
KIADB Industrial Area
Hebbal, Hootagalli
Mysore - 570018
Karnataka, INDIA

Contact Person: Mr. A. B. Deshpande
Head - Quality Assurance & Customer Support
Medical Equipment & Systems
Larsen & Toubro Limited
Phone: 011-91-821-402561
Fax: 011-91-821-2402468
E-mail: DeshpandeAB@myw.ltindia.com

Date Prepared: November 20, 2003

2. DEVICE NAME

Proprietary Name:	Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System
Common/Usual Name:	Ultrasound System and Transducers
Classification Name:	Ultrasonic Pulsed Doppler Imaging System (21 CFR 892.1550, 90 IYN) Ultrasonic Pulsed Echo Imaging System (21 CFR 892.1560, 90 IYO) Diagnostic Ultrasound Transducer (21 CFR 892.1570, 90-ITX)

3. PREDICATE DEVICES

TETRAD 2300 E/U Ultrasound Imaging System with Color Flow Doppler Imaging (K946277), and Acuson Aspen System (K991805).

4. INTENDED USE

The Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System is intended for diagnostic ultrasound imaging or fluid flow analysis

of the human body; specific indications for use a tabulated in Section 4.3 of this submission.

5. DEVICE DESCRIPTION

Technical specifications for the Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System are as follows:

System Specifications

Type of protection against electric shocks	Class I
Degree of protection against electric shock	
for ultrasound probes	Type "BF"
For ECG electrodes	Type 'CF"
Degree of protection against hazard of explosion	Not protected
Degree of protections against ingress of liquids	IPXO
Power Requirements	
AC input	110 V AC 60 Hz single phase
Fuse	Two (2) 12A, slow blow, glass cartridge fuses in Line and Neutral
Load	Total: 1000A (System: 850 VA, Aux. Output: 150 VA)
Leakage	<145µA as per UL2601

General Specifications

Dimensions	1400mm(H) x 620mm(W) x 800mm(D)
Weight	120kg/270 lbs. (approximate)
Keyboard console rotation	
Rotation of console	Keyboard +/- 30°
Monitor tilt	+/- 30

External Ports	FDD CDRW Parallel port-inkjet printer USB port (rear panel) Laser printer RJ45 (LAN) port – Networking VGA port-SVGA monitor (slave) DIN Port-Footswitch Audio Port (real panel) Relay out Audio port (front panel) Headphone USB port (front panel) Thumb Drive Auxiliary power – additional Monitor
Monitor	15" SVGA monitor
Size of image	512 x 512 pixels
Operating temperature	10°C to 35°C
Humidity	80% RH
Safety	The product shall comply to the Safety Standards as per IEC 60601
Language	English

Technical Specifications

Operating System	Windows 2000
Probe Connectors	Two (2) ITT Cannon DL 156 connectors
Options	Colour Doppler PW Spectral Doppler
Gain	Overall gain controls for B & M modes (combined) D mode (Pulsed Doppler) C mode (Colour Doppler) P mode (Power/amplitude Doppler)
Power	Acoustic power control
TGC	Eight (8) slide switches for eight (8) depths
Image Processing General	Focus Multifocus Dynamic Range Sensitivity Persistence

Pre-processing	Temporal averaging Tissue discrimination Colour maps Thresholding Flash Suppression Edge Enhancement
M mode speed	2s, 4s, and 8s
D mode speed	2s, 4s, and 8s
Image Memory Size	512 x 512 x 8 bits
Grey Scale	256 levels

Image Specifications

Array types	Linear Curved Linear
Maximum array size	128 elements
Maximum symmetric aperture	48 elements
Scan conversion	PCI card color (8 bit grayscale output with 256 shades)
Display	24 bit color Selectable gray maps
Imaging resolution	(Best case, measured in water, assuming f/2 for lateral resolution measurement)

Freq.	Axial	Lateral
3 MHz	1 mm	1.025 mm
5 MHz	0.65 mm	0.75 mm
7.5 MHz	0.41	0.49 mm

Magnification	Magnification factors: 1.5, 1.8, 2.0 real time images
Image orientation	Horizontal (left/right) and Vertical (up/down) inversion of image
Probes supported	Standard Abdominal Endovaginal Tightly curved Cardiovascular Vascular
Multi-Frequency	Supported on all probes
Center Frequency	3.0 –12.0 MHz (20 MHz upper band edge)

Transmit Focus	Multi-zones, 1 to 8 zones, interleaved
Received focus methods	Dynamic Updated every 1.5 mm in depth Errors ≤ 10° in the 3 to 12 MHz range Envelope delays switched between transmit zones Transmit focus increment – 10 ns Transmit waveform – bipolar burst 150 V p-p max

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System is substantially equivalent to the TETRAD 2300 E/U Ultrasound Imaging System with Color Flow Doppler Imaging, and to the Acuson Aspen System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

Larsen & Toubro Limited
% Mr. Juergen Welte
510(k) Program Manager
TUV Rheinland of North America
1279 Quarry Lane, Suite A
PLEASANTON CA 94566

Re: K040409
Trade Name: Senorita Colour Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regualtion Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and IYX
Dated: January 26, 2004
Received: February 18, 2004

Dear Mr. Welte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Senorita Colour Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

TC-101-CP (2.5 – 5.0 MHz Curved Linear Array Transducer)
TC-110-CP (2.5 – 4.5 MHz Curved Linear Transducer)
TC-200-LP (6 – 9 MHz Linear Transducer)

TC-201-LP (5 – 8 MHz Linear Transducer)
TC-400-EP (Curved Linear 5 – 9 MHz Transvaginal Transducer)

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M[a]	PWD[b]	CWD	Color Doppler[c]	Combined Modes[d]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	
	Abdominal	N	N	N		N	N	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	
	Cardiac Pediatric	N	N	N		N	N	
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

N: subject of this submission.
[a] Includes B+M.
[b] Includes B+PWD.
[c] Includes Color Doppler (CD) ; Amplitude Doppler (AD); B+CD; B+AD.
[d] B+PWD+CD; B+PWD+AD
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040409

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System_____
Transducer: TC-101-CP (2.5 – 5.0 MHz Curved Linear Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M[a]	PWD[b]	CWD	Color Doppler[c]	Combined Modes[d]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	
	Abdominal	N	N	N		N	N	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N: subject of this submission.
[a] Includes B+M.
[b] Includes B+PWD.
[c] Includes Color Doppler (CD) ; Amplitude Doppler (AD); B+CD; B+AD.
[d] B+PWD+CD; B+PWD+AD
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040409

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System_____
Transducer: TC-110-CP (2.5 – 4.5 MHz Curved Linear Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M[a]	PWD[b]	CWD	Color Doppler[c]	Combined Modes[d]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	
	Cardiac Pediatric	N	N	N		N	N	
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N: subject of this submission.
[a] Includes B+M.
[b] Includes B+PWD.
[c] Includes Color Doppler (CD) ; Amplitude Doppler (AD); B+CD; B+AD.
[d] B+PWD+CD; B+PWD+AD
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
Y = Yes, intended for this mode/use combination.

Prescription Use (per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040409

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System_____
Transducer: TC-200-LP (6 – 9 MHz Linear Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M[a]	PWD[b]	CWD	Color Doppler[c]	Combined Modes[c]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	
	Abdominal	N	N	N		N	N	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

N: subject of this submission.
[a] Includes B+M.
[b] Includes B+PWD.
[c] Includes Color Doppler (CD) ; Amplitude Doppler (AD); B+CD; B+AD.
[d] B+PWD+CD; B+PWD+AD
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040409

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ____Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System_____
Transducer: TC-201-LP (5 – 8 MHz Linear Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M[a]	PWD[b]	CWD	Color Doppler[c]	Combined Modes[d]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	N	
	Abdominal	N	N	N		N	N	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	
	Small Organ (Thyroid, Breast, Testes, etc.)	N	N	N		N	N	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	N	
	Other (Specify)							

N: subject of this submission.
[a] Includes B+M.
[b] Includes B+PWD.
[c] Includes Color Doppler (CD) ; Amplitude Doppler (AD); B+CD; B+AD.
[d] B+PWD+CD; B+PWD+AD
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040409

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Larsen & Toubro Limited SENORITA Colour Doppler Ultrasound System
Transducer: TC-400-EP (Curved Linear 5 – 9 MHz Transvaginal Transducer)
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M[a]	PWD[b]	CWD	Color Doppler[c]	Combined Modes[d]	Other
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N: subject of this submission.
[a] Includes B+M.
[b] Includes B+PWD.
[c] Includes Color Doppler (CD) ; Amplitude Doppler (AD); B+CD; B+AD.
[d] B+PWD+CD; B+PWD+AD
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040409